REMARKS/ARGUMENTS

The Pending Claims

Claims 1-55 and 57-77 are pending.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. Claim 17 has been amended to recite that the nucleic acid encodes the amino acid sequence of SEQ ID NO: 1 as supported by originally filed claim 1. Claim 57 has been amended to recite human immunodeficiency virus (HIV) as supported by the specification at, for example, paragraph 00100. Claims 64 and 65 have been amended to clarify claim language by deleting the phrase "any of."

No new matter has been added by way of these amendments.

Summary of the Office Action

The Office objects to claims 64 and 65 for alleged informalities.

The Office rejects claims 1, 3-52, 55, and 57-77 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Office rejects claims 37-51 and 60-77 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

The Office objects to claims 2, 53, and 54 as depending from a rejected base claim.

Reconsideration of these objections and rejections is hereby requested.

Discussion of the Objections to Claims 64 and 65

Claims 64 and 65 have been amended to no longer recite "any of" as suggested by the Office. The rejections of the base claims from which claims 2, 53, and 54 depend are believed to be overcome as described below.

Therefore, Applicants believe that the objections to these claims are moot and should be withdrawn.

Discussion of the Written Description Rejections

The Office contends that there is insufficient descriptive support for variants or fragments of the protein of SEQ ID NO: 1.

Applicants respectfully submit that the inventive antiviral protein is completely enabled and adequately described in the specification. Applicants provide the amino acid sequence encoding scytovirin in SEQ ID NO: 1. Generating mutations in the amino acid sequence (or nucleic acid sequence that encodes the amino acid sequence) to produce a mutant scytovirin coding sequence that encodes a functional antiviral protein is described in the specification at, for example, paragraphs 0025-0031. Methods of screening candidate proteins for antiviral activity are provided in the specification at, for example, Example 5.

Thus, one of ordinary skill in the art, having the complete amino acid sequence of scytovirin (i.e., SEQ ID NO: 1, which is only 95 amino acids in length) would be able to generate scytovirin fragments and variants and to screen them for antiviral activity using routine methods as taught by the specification. Accordingly, one of ordinary skill in the art would only need to perform routine experimentation, which is not *undue* experimentation.

Applicants have generated fragments and variants of scytovirin which retain antiviral activity, as described in the specification at, for example, paragraphs 0025-0031, and a Declaration under 37 C.F.R. § 1.132, executed by Barry R. O'Keefe and submitted herewith. In addition, according to Dr. O'Keefe, one of ordinary skill in the art has the requisite knowledge and ability to generate further mutations in SEQ ID NO: 1 to obtain mutants of SEQ ID NO: 1 retaining antiviral activity. For example, the three-dimensional structure of the scytovirin protein can be obtained based on the amino acid sequence of SEQ ID NO: 1. The ordinarily skilled artisan, upon mapping the topological conformation of the protein, can determine which amino acid residues can be manipulated, while not disrupting protein folding. Likewise, it is understood in the art that surface hydrophobicity is responsible for protein-protein interactions. The ordinarily skilled artisan can map hydrophobicity surface clusters on the scytovirin protein to determine which amino acid residues can likely be manipulated, such that hydrophobicity characteristics of these clusters are essentially unchanged. Thus, using the specification as a guide, one of ordinary skill in the art can make and use the inventive antiviral proteins with routine experimentation.

The Office contends that there is insufficient descriptive support for a genus of nucleic acids that have been isolated or purified from *Scytonema varium* as recited in claim 17. Claim 17 has been amended to recite that the nucleic acid encodes the amino acid sequence of SEQ ID NO: 1.

The Office contends that there is insufficient descriptive support for the genus of antibodies recited in claim 57. Claim 57 has been amended to recite that the antibody has an internal image of HIV gp120. The specification describes the generation and use (e.g., as a vaccine) of antibodies with the internal image of HIV gp120 at, for example, paragraphs 0099-00102. Additionally, the specification describes methods of selecting an anti-scytovirin antibody that has an internal image of HIV gp120 (see, e.g., paragraph 00100). Accordingly, based on the description in the specification, one of ordinary skill in the art can make and use the inventive anti-scytovirin antibodies with routine experimentation.

For the above-described reasons, the pending claims are fully described by the specification. Therefore, Applicants request that the written description rejections be withdrawn.

Discussion of the Enablement Rejections

The Office contends that the specification is not enabling for methods of inhibiting HIV virus infection of a host or of inhibiting infection by viruses other than HIV. In particular, the Office contends that the results of *in vitro* assays are not an indication of *in vivo* results. Moreover, the Office contends that the application provides no demonstration that scytovirin is effective against any virus other than HIV.

The antiviral activity of scytovirin is demonstrated in an *in vitro* antiviral assay that reasonably predicts antiviral activity *in vivo* (see, e.g., Example 5). This *in vitro* assay is accepted by those of ordinary skill in the art as reasonably predictive of activity *in vivo*. The specification describes the use of scytovirin to inhibit viral infections (e.g., HIV, HTLV, FIV, FLV, SIV, MLV, BLV, BIV, hepatitis virus, arbovirus, herpes virus, measles virus, mumps virus, rubella virus, pox virus, influenza virus, and Ebola virus) *in vivo*, including appropriate doses of scytovirin, formulations, and methods of administration (see, e.g., paragraphs 0057, 0063, 0075, 0086, and 0089).

Applicants also have demonstrated that scytovirins can inhibit a viral infection *in vivo* using a mouse model. The results of an exemplary *in vivo* assay are provided in the enclosed Declaration under 37 C.F.R. § 1.132, executed by Barry O'Keefe. The results demonstrate that scytovirin, administered subcutaneously to mice, inhibited viral infection due to challenge with mouse-adapted Ebola (Zaire) virus. The animals demonstrated 60% survival with scytovirin treatment as opposed to 20% survival with a negative control.

Additionally, Applicants have demonstrated that scytovirin is effective in inhibiting influenza infection. Exemplary experiments are set forth in the enclosed Declaration under 37 C.F.R. § 1.132, executed by Barry O'Keefe.

Thus, the ability of the inventive antiviral proteins to inhibit a viral infection (e.g., HIV, influenza, and Ebola) has been proven in cell assays and in hosts, such as mice. Based on the description in the specification of scytovirin's antiviral effects (which are confirmed by the experiments described in the enclosed Declaration under 37 C.F.R. § 1.132, executed by Barry O'Keefe), one of ordinary skill in the art would have understood how to make and use the inventive antiviral proteins.

The Office contends that the specification does not provide an enabling disclosure for claims 60-63, which are directed to a method of inhibiting viral infection of a mammal comprising the administration of an antibody that binds to scytovirin.

The specification describes the use of an anti-scytovirin antibody (e.g., that has an internal image of gp120) as a vaccine (see, e.g., paragraphs 00100-00101). For example, an anti-scytovirin antibody that has an internal image of gp120 induces an immune response (i.e., the production of antibodies) against gp120, thereby inhibiting infection in a host of a virus expressing gp120. Additionally, as described above, the specification provides methods to generate and select anti-scytovirin antibodies with the internal image of HIV gp120 (see, e.g., paragraphs 0097-00102). Accordingly, the specification effectively describes and enables the use of an anti-scytovirin antibody to inhibit a viral infection of a mammal.

For the above-described reasons, the pending claims are sufficiently enabled by the specification. Therefore, Applicants request that the enablement rejections be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,

Rachel J. Mejdrich, Reg. No. 53,477
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: August 1, 2007